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10/037,296	12/21/2001	Bjorn Dahlback	INL-054DV	4472
21323	7590	01/19/2005	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP			SAUNDERS, DAVID A	
HIGH STREET TOWER				
125 HIGH STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02110			1644	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	037,296	Applicant(s)	DAHLBACK et al
Examiner	SAUNDERS	Group Art Unit	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on 10/15/04
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 20-22, 31, 33-42, 44-58 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) 31, 44-45, 58 is/are allowed.
- Claim(s) 20-22, 33-42, 46-48, 50-56 is/are rejected.
- Claim(s) 49, 57 is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/04 (an amendment and exhibits) has been entered.

Following entry of this amendment, claims 20-22, 31, 33-42 and 44-58 are pending and under examination. The following corrections pertain to the office action mailed 7/16/04:

On form PTOL -326 under "Disposition of claims" the listing of claims "20-22, 31 and 33-47" should have appeared by box 6, instead of box 8.

At page 3, line 8, "31" should have read as --20--. At line 9 "proteins" should have read as --Protein S--.

At page 5, line 4 "2-22" should have read as --20-22--.

The disclosure is objected to because of the following informalities: At page 3, line 27 "micrometer" should be replaced with --microtitre--.

Appropriate correction is required.

At page 4, lines 13-14, referring to claim 1 is not appropriate for an application with claims drawn to a kit.

Applicant's amendment of 10/15/04 has overcome the previously stated ground of rejection render 37 CFR 1.75 c). new grounds of objection are stated below.

Claim 48 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation in claim 48 that the "first site is the C4BP binding site in Protein S" is inherent to the nature of the ligand defined in base claim 20, given the recitations therein (lines 3 and 6) of the "protein S binding site in C4BP".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Due to applicant's amendment of 10/15/04, the previously stated grounds of rejection under 35 USC 112, second paragraph have been overcome except for claims 34 and 46. This rejection and new grounds under this statute are maintained as follows.

Claims 34-36 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 35-36 "the antibody" lacks antecedent basis. It is believed dependency from claim 49, instead of 50, is intended.

Claims 34 and 46 have an improper Markush Group. The "matrix" member is not clearly different in scope from the "carrier" of claims 21 and 45. Applicant's disclosure has used the terms "carrier" and "solid matrix" interchangeably; thus the member recited as "matrix" fails to further define the "carrier" in any manner.

The mere fact that applicant's amendment of 10/15/04 has cancelled the modifier "solid" before "carrier" does not overcome the confusion, since the terms "solid" and "matrix" themselves appear to be used in an indistinguishable manner in the disclosure.

Applicant's amendment has overcome 112, first paragraph issues of record, except for those pertaining to claims of these claims are maintained below.

Claims 33-34 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter.

In claims 33-34 and 46-47 "a bead" lacks support. The only original recitation of "beads" is at page 13, line 29, wherein the beads are specifically disclosed as being "of polystyrene" and "having a diameter of about 5 mm." Applicant has improperly broadened the scope of the nature of the bead.

In claims 34 and 46 "gel" lacks support. Examiner finds no "gel" taught in the para. spanning pages 13-14.

In claims 34 and 46 "sheet" lacks support, except for those that are "nitrocellulose – or nylon-based webs." See page 13, line 31. Applicant has improperly broadened the nature of the "sheets".

Applicant's urgings at page 9 of the amendment have indicated that the disclosed "polystyrene" material and "5 mm" diameter of the beads disclosed at page 13, line 29 would have been understood by one of skill to be merely exemplary. The examiner

grants that one of skill could well have understood the disclosure in such manner. However, the office takes this understanding to be one of obviousness -- i.e. given a narrow disclosure of beads made of a particular material and of a particular dimension, one of skill would have readily found it obvious to likewise use beads made of other conventional materials and of other typical dimensions. Obviousness does not provide for proper descriptive support. *Lockwood v. American Airlines* 41 USPQ2d 1961.

The examiner also considers the mere recitation of "bead", without the originally disclosed material and dimensional limits, to be a new subgenus ("beads") among the genus of "carriers". An originally described genus does not support a new subgenus, if only a species of the subgenus is originally recited. *In re Smith* 173 USPQ 679.

Applicant further argues that a generic bead is supported by the fact that the disclosed cross-linked dextran products of Sephadex are beads. Thus urging merely points to one more species of bead; applicant's disclosure has thus disclosed two kinds of beads – polystyrene (of a particular dimension) and Sephadex. The recitation of two species does not convey to one that applicant was intending to disclose beads of any material.

Applicant has also urged that the mention of Sephadex in the specification supports the term "gel", since Sephadex is a "bead-formed gel". Again applicant is attempting to claim a new subgenus based upon what might have been obvious, or is attempting to claim a new subgenus by disclosure of only one species therein. Further the examiner does not consider Sephadex beads to be representative of all members of the subgenus of "gels". Sephadex and related products, such as Bio-Gel, are solid

phase beads that can separate materials, based on molecular weight, by gel –filtration when the beads are packed in a column. The term "gel" however would also encompass cast gels –e.g. in a tube or in a dish/well – which are not in bead form. Thus by the mere disclosure of "Sephadex" one could not envision whether the subgenus of "gels" encompasses only bead gels or also other kinds of gels, including cast gels.

Applicant has urged that the rejection concerning the subgenus of "Sheets" has been overcome by amending claims 34 and 46 to recite that a structural feature of the solid carrier is being claimed. This change does not overcome because it is not clear from page 13, lines 26-32 that applicant was setting forth structural features; it appears, to the contrary, that applicant was setting forth a listing of compositions of solid carriers, since the sentence starts with the recitation "useful solid materials are well known in the art and are composed of water insoluble materials."

Further, even if what was set forth at page 13 did, in fact, set forth structures, the recitation "of sheet" is overly broad because the structure set forth is a "web". Since there can be sheets which are not webs –e.g. a sheet of polystyrene or of aluminum – applicant is now claiming broader than one of skill would have appreciated from the original disclosure.

Applicant's urgings filed 10/15/04 have been considered but are unconvincing.

New grounds of rejection under 112, first paragraph are set forth below.

Claims 2-22, 33-42, 46, 48 and 50-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 20, 34, 46 and 50-51 recite new matter.

In claim 20, in the second paragraph, the generic recitation of "reagent" is not supported, because applicant has disclosed no reagent for binding protein S (at a site distinct from the first site) except for an antibody or its fragment. Scope is further broadened, since nothing in the claim requires that the reagent be "specific" for protein S. Applicant has unduly broadened the claim.

Further, even if the term "reagent" had been originally recited, a mere antibody to protein S is not representative of the entire genus of "reagents" that bind to protein S. One cannot envision what the other members of the genus might be – e.g. lectins, non-antibody receptors, chelators, polyionic macromolecules etc. Applicant has thus not adequately described the genus of reagents that bind Protein S at the recited site(s).

With respect to claims 34 and 46 the term "strip" was previously recited. The examiner presently finds this subgenus not supported, for the same reasons set forth supra regarding the term "sheet". The examiner finds the original disclosure at page 13, lines 31-32 as setting forth both "sheets" and "strips" as examples ("such as" is recited) of "nitrocellulose – or nylon –based webs". Thus the "strip", as well as the "sheet" was disclosed as being no broader than a sheet or strip of nitrocellulose or nylon, with either material having a web structure.

In new claims 50-51 the terms "dextrin", "polyacrylamide", "nitrocellulose", and "nylon" are broader than originally disclosed. At page 13, lines 26<sup>+</sup> "dextran" and "polyacrylamide" were disclosed as limited to being "cross-linked" in each case. Likewise, at page 13, line 31, "nitrocellulose" and "nylon" were disclosed as limited to being "cross-linked" in each case. Likewise, at page 13, line 31, "nitrocellulose" and "nylon" were disclosed as limited to being in "web" form. Again applicant has improperly broadened the nature of the invention, based upon what might have been obvious and upon the erroneous position that one species can support a new subgenus.

Claims 20-22, 33-42, 48, 50 and 52-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for provision of a "reagent" which is an antibody (or fragment thereof) specific for Protein S, does not reasonably provide enablement for a generic "reagent" which binds protein S. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to produce the invention commensurate in scope with these claims. As noted supra, under the description requirement of 112, applicant has disclosed no reagents that bind protein S at a site "distinct from the first site", except for antibodies. Those of skill do not know of other plasma proteins, which can specifically bind to Protein S. Applicant has given the reader no direction as to what kind of specific binding reagents, other than antibodies or to be used. There is no disclosure of a particular lectin, natural receptor, chelator, synthetic macromolecule etc that specifically binds to the recited site. Applicant is thus inviting one to conduct undue

experimentation to obtain reagents, which have not been described, without even a hint of what starting materials should be screened for protein S binding activity.

Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All prior art rejections of record have been overcome by the amendment of 10/15/04.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-<sup>3</sup>~~272~~-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/037,296  
Art Unit: 1616

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Saunders/LR  
December 20, 2004

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ART UNIT 1616